**Citation:**

Swift PA, Markandu ND, Sagnella GA, He FJ, MacGregor GA. Modest salt reduction reduces blood pressure and urine protein excretion in black hypertensives: A randomized control trial. *Hypertension*. 2005 Aug; 46(2): 308-312. Epub 2005

**PubMed ID:** 15983240

**Study Design:**

Randomized crossover trial

**Class:**

A - Click here for explanation of classification scheme.

**Research Design and Implementation Rating:**

POSITIVE: See Research Design and Implementation Criteria Checklist below.

**Research Purpose:**

- To determine the effect of salt reduction on blood pressure (BP)
- To determine the effect on urine protein excretion.

**Inclusion Criteria:**

- Black hypertensives [systolic blood pressure (SBP) ≥140mmHg or diastolic blood pressure (DBP) of ≥90mmHg] of African or African-Caribbean origin
- Participants had not been treated with pharmacological antihypertensive agents in the preceding four weeks or diuretics in the preceding eight weeks.

**Exclusion Criteria:**

- Severe hypertension (HTN) (SBP ≥200mmHg or DBP ≥110mmHg)
- Evidence of secondary HTN, previous stroke
- Ischemic heart disease
- Cardiac failure
- Diabetes mellitus
- Pregnancy
- Liver disease
- Significant renal insufficiency (creatinine higher than 160mmol per L)
- Overt proteinuria (higher than 300mg of urinary protein per 24 hours).

**Description of Study Protocol:**

**Recruitment**

Black hypertensives (SBP ≥140mmHg or DBP ≥ 90mmHg) of African or African-Caribbean

origin were invited to participate in the study.

**Design**

Randomized crossover study.

**Blinding Used**

Double-blind study.

**Intervention**

- Run-in periods: Study participants were asked to continue on their usual diet for a run-in period of four weeks
- An additional two-week run-in period on reduced salt, in which participants were given written and verbal advice by specialist nurses on how to reduce salt, with a view to achieving an intake of approximately 5g daily
- Intervention period: 12 slow sodium tablets (10mmol sodium per tablet) daily or 12 matched placebo tablets for four weeks each.

**Statistical Analysis**

- Paired student T-test
- Wilcoxon sign ranks test
- Correlation analysis.

**Data Collection Summary:**

**Timing of Measurements**

Blood pressure and other measurements were made at the end of each run-in period and at the end of each four-week period on slow sodium or placebo.

**Dependent Variables**

- Blood pressure was measured by trained specialist nurses. The mean of the last three readings was recorded for analysis
- 24-hour ambulatory BP monitoring was performed using SpaceLab 90207 devices. They were fitted in the mornings and BP recordings were taken at half-hourly intervals during the day (from 9:00 a.m. to 10:00 p.m.) and at hourly intervals overnight (from 10:00 p.m. to 9:00 a.m.).

**Independent Variables**

Slow sodium vs. placebo tablets.

**Control Variables**

Subjects were themselves control (cross-over design).

**Description of Actual Data Sample:**

- *Initial N:* 47
- *Attrition (final N):* 40 (17 males and 23 females); one withdrew during the run-in phase, and

six dropped out after randomization
- *Age:* 50±10 years
- *Ethnicity:* African or African-Caribbean origin
- *Other relevant demographics:* 100% hypertensives; normal kidney function
- *Anthropometrics:* BMI=28±4kg/$m^2$
- *Location:* United Kingdom.

**Summary of Results:**

**Key Findings**

- Reducing salt intake from approximately 10 to 5g per day resulted in significant and important falls in BP (i.e., an 8mmHg fall in SBP and 3mmHg fall in DBP) as well as falls in urine protein excretion (a risk factor for development and progression of renal disease) in black hypertensives
- This fall in BP was sustained over a 24-hour period, with significant falls in ambulatory blood pressure (ABP) measured in the day and at night.

**Other Findings**

- With approximately 5g per day reduction in salt intake (verified by luminary sodium excretion), BP fell from 159/101±13/8 to 151/98±13/8mm Hg [i.e., a fall in SBP of 8±13mmHg (P<0.001) and DBP of 3±7mmHg (P<0.009)]
- There were significant falls in mean daytime and nighttime ABPs, with the reduction in salt intake (mean 24-hour reduction of 7/3mmHg)
- Urine protein excretion fell from 93±48mg per 24 hours on slow sodium to 75±30mg per 24 hours on placebo. Thus, the mean fall in urine protein excretion was 18±39mg per 24 hours (P<0.008) with salt reduction
- There was NS relationship between the change in urine protein excretion and the change in SBP (R=0.07; P=0.70) or change in DBP (R=0.19; P=0.26) with salt reduction.

**Author Conclusion:**

A modest reduction in salt intake from 10 to 5g per day reduced BP and urine protein excretion in non-diabetic black hypertensives.

***Reviewer Comments:***

- *This is a short-term study so the long-term effects of sodium restriction is still unclear*
- *Participants were highly selective group of subjects so the generalizability of the study results is also unclear.*

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***Research Design and Implementation Criteria Checklist: Primary Research***

**Relevance Questions**

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| 1. | Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies) | N/A |
| 2. | Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about? | N/A |
| 3. | Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice? | N/A |
| 4. | Is the intervention or procedure feasible? (NA for some epidemiological studies) | N/A |

**Validity Questions**

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|---|---|---|
| **1.** | **Was the research question clearly stated?** | Yes |
| 1.1. | Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified? | Yes |
| 1.2. | Was (were) the outcome(s) [dependent variable(s)] clearly indicated? | Yes |
| 1.3. | Were the target population and setting specified? | Yes |
| **2.** | **Was the selection of study subjects/patients free from bias?** | Yes |
| 2.1. | Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study? | Yes |
| 2.2. | Were criteria applied equally to all study groups? | Yes |
| 2.3. | Were health, demographics, and other characteristics of subjects described? | Yes |
| 2.4. | Were the subjects/patients a representative sample of the relevant population? | Yes |
| **3.** | **Were study groups comparable?** | Yes |
| 3.1. | Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT) | Yes |
| 3.2. | Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline? | Yes |
| 3.3. | Were concurrent controls used? (Concurrent preferred over historical controls.) | Yes |
| 3.4. | If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis? | N/A |

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| 3.5. | If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.) | N/A |
| 3.6. | If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")? | N/A |
| **4.** | **Was method of handling withdrawals described?** | Yes |
| 4.1. | Were follow-up methods described and the same for all groups? | Yes |
| 4.2. | Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.) | Yes |
| 4.3. | Were all enrolled subjects/patients (in the original sample) accounted for? | No |
| 4.4. | Were reasons for withdrawals similar across groups? | Yes |
| 4.5. | If diagnostic test, was decision to perform reference test not dependent on results of test under study? | N/A |
| **5.** | **Was blinding used to prevent introduction of bias?** | Yes |
| 5.1. | In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate? | Yes |
| 5.2. | Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.) | ??? |
| 5.3. | In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded? | N/A |
| 5.4. | In case control study, was case definition explicit and case ascertainment not influenced by exposure status? | N/A |
| 5.5. | In diagnostic study, were test results blinded to patient history and other test results? | N/A |
| **6.** | **Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?** | Yes |
| 6.1. | In RCT or other intervention trial, were protocols described for all regimens studied? | Yes |
| 6.2. | In observational study, were interventions, study settings, and clinicians/provider described? | N/A |
| 6.3. | Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect? | ??? |
| 6.4. | Was the amount of exposure and, if relevant, subject/patient compliance measured? | Yes |

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| 6.5. | Were co-interventions (e.g., ancillary treatments, other therapies) described? | N/A |
| 6.6. | Were extra or unplanned treatments described? | N/A |
| 6.7. | Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups? | Yes |
| 6.8. | In diagnostic study, were details of test administration and replication sufficient? | N/A |
| **7.** | **Were outcomes clearly defined and the measurements valid and reliable?** | Yes |
| 7.1. | Were primary and secondary endpoints described and relevant to the question? | Yes |
| 7.2. | Were nutrition measures appropriate to question and outcomes of concern? | Yes |
| 7.3. | Was the period of follow-up long enough for important outcome(s) to occur? | N/A |
| 7.4. | Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures? | N/A |
| 7.5. | Was the measurement of effect at an appropriate level of precision? | N/A |
| 7.6. | Were other factors accounted for (measured) that could affect outcomes? | N/A |
| 7.7. | Were the measurements conducted consistently across groups? | N/A |
| **8.** | **Was the statistical analysis appropriate for the study design and type of outcome indicators?** | Yes |
| 8.1. | Were statistical analyses adequately described and the results reported appropriately? | Yes |
| 8.2. | Were correct statistical tests used and assumptions of test not violated? | Yes |
| 8.3. | Were statistics reported with levels of significance and/or confidence intervals? | Yes |
| 8.4. | Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)? | N/A |
| 8.5. | Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)? | Yes |
| 8.6. | Was clinical significance as well as statistical significance reported? | No |
| 8.7. | If negative findings, was a power calculation reported to address type 2 error? | N/A |
| **9.** | **Are conclusions supported by results with biases and limitations taken into consideration?** | No |
| 9.1. | Is there a discussion of findings? | Yes |

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| 9.2. | Are biases and study limitations identified and discussed? | No |
| **10.** | **Is bias due to study's funding or sponsorship unlikely?** | Yes |
| 10.1. | Were sources of funding and investigators' affiliations described? | Yes |
| 10.2. | Was the study free from apparent conflict of interest? | Yes |